Exhibit D

HIGHLY CONFIDENTIAL

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA CORPORATION, JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, JANSSEN RESEARCH AND DEVELOPMENT, LLC, and CILAG GMBH INTERNATIONAL, Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC., Defendant.	**Civil Action No. 17-5005 (consolidated)** **Contains Highly Confidential Information**

OPENING EXPERT REPORT OF FRITZ BLATTER, PH.D.

I, Fritz Blatter, Ph.D, submit the following report on behalf of Mitsubishi Tanabe Pharma Corporation, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH International (collectively, "Plaintiffs") in this action.

I. EXPERT QUALIFICATIONS

A. Area of Expertise

1. I am an expert in the fields of pharmaceutical solid-state forms, organic chemistry, inorganic chemistry, and materials testing using X-ray diffraction, microscopy, including polarized light microscopy, and Raman spectroscopy.

B. Educational Background

2. In 1985, I obtained a Diploma in Chemistry, the equivalent to a Master of Science degree, from the Department of Chemistry at the University of Bern located in Bern, Switzerland. I also studied subjects in physics, mathematics, and biology in the course of obtaining my degree.

3. In 1989, I obtained a Major in Human Medicine, the equivalent to a Bachelor of Science degree, from the Faculty of Medicine at the University of Bern.

4. From 1985 until 1989, I went on to study with Professor E. Schumacher and obtained a Ph.D. in Chemistry from the Department of Chemistry at the University of Bern. I studied topics in zeolites, clusters, catalysis and small particles. During the course of my degree, I also taught undergraduate students in general, inorganic, and physical chemistry.

5. From 1989-1990, I was a Postdoctoral Research Associate at IBM Research Laboratories in Zürich, Switzerland with Dr. K. W. Blazey and Nobel Laureate Prof. K.A. Müller. In addition, from 1991 to 1995, I was a Postdoctoral Research Associate at the University of California Berkeley in the Physical Biosciences Division, Melvin Calvin Laboratory of Ernest Orlando Lawrence Berkley National Laboratory with Dr. Heinz Frei.

C. Relevant Professional Experience

6. Currently, I am a "Mitglied des Kaders" (Partner) at Solvias AG, in Kaiseraugst, Switzerland ("Solvias"). I am also the Deputy Head of Department and Project Manager in the Department for Solid State Development. I specialize in projects related to chemical and analytical development of new drug substances. I have continuously developed and improved my skills in a variety of analytical testing methods, including, but not limited to, powder X-ray diffraction ("PXRD"), microscopy, and Raman spectroscopy, and those testing methods are regularly carried out in my lab at Solvias.

7. Prior to my current position, I worked at Novartis Services AG as the Head of Laboratory of Solids & Interfaces from 1997-1999. As the Laboratory Head, I researched and managed projects to resolve problems of importance to the chemical and pharmaceutical industry, including issues relating to properties of solids, polymorphism of drugs, crystallizations, drying, milling, thermal analysis, colloid and interface science, organic solid state chemistry, and spectroscopy.

8. For over 20 years, I have used Raman spectroscopy, PXRD, and microscopy among other techniques in my research efforts.

9. Throughout my professional career, I have been associated with laboratories that provide a complete range of analytical services covering all aspects of pharmaceutical and specialty chemicals. These laboratories have been recognized for their expertise in the characterization of drug substances and dosage forms, solving manufacturing problems associated with the drug substance or drug product, providing pharmacopoeia-based analytical testing, developing solid-state analytical methods, stabilizing drugs in the solid-state, and consulting on regulatory issues.

10. I am the author (or co-author) of more than 30 publications in peer-reviewed scientific journals. I am also a co-inventor of 46 issued United States patents and a co-inventor or sole inventor of about 25 pending patent applications worldwide.

11. For a complete list of my professional experiences, publications and lectures, please see my curriculum vitae attached hereto as Exhibit 1.

D. Previous Testimonial Experience

12. Within the past four years, I testified at a deposition or at trial for the following matters:

- *LEO Pharma A/S, LEO Pharma, Inc. v. TEVA Canada and Minister of Health*, T-1791-13 (April 2015 Deposition in London); and
- *Pfizer Inc. et al. v. Anchen Pharmaceuticals, Inc. et al.*, 12-cv-808 (SLR), D. Del. (June and July 2014 Depositions in London and New York).

E. Compensation

13. I have been retained by Plaintiffs as an expert witness in the above-captioned patent litigation brought by Plaintiffs against Defendant Zydus Pharmaceuticals (USA), Inc. ("Zydus"). I have no financial interest in the outcome of this case. Solvias is billing Plaintiffs 380 CHF (~ 390 USD) per hour for expert activities, 290 CHF (~ 300 USD) per hour for project work related to testing and laboratory work involving other technical personnel at Solvias, and 200 CHF (~205 USD) for travel time and other administrative type tasks related to the project. Solvias is an independent provider of scientific services and has relationships with numerous major pharmaceutical companies world-wide. My compensation does not depend in any way on the outcome of this litigation.

II. MATERIALS CONSIDERED

14. The opinions that I express in this report are based on the information and evidence currently available to me. A list of materials that I considered in forming my opinions set forth in this report is attached as Exhibit 2. I also relied on my general knowledge, experience, and scientific analysis.

III. OVERVIEW OF OPINIONS

15. I was asked by counsel for Plaintiffs to conduct certain testing on the active pharmaceutical ingredients ("API") described in Zydus's Abbreviated New Drug Applications ("ANDAs"). Specifically, I was asked to analyze samples of Zydus's API using polarized light microscopy and Raman spectroscopy.

16. [redacted]

17. [redacted]

18. [redacted]

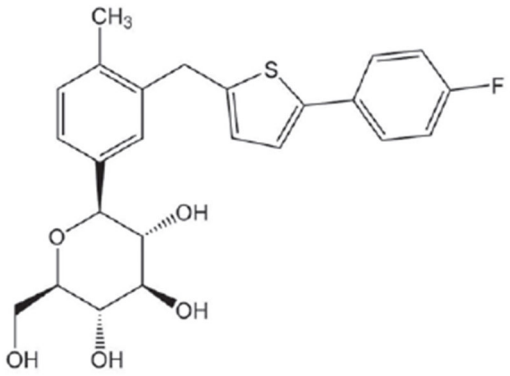
19. [redacted]

20. This report sets forth my analyses and opinions based on the materials I have considered thus far, as well as the bases for my opinions.

IV. RULE 26(a)(2)(B) DISCLOSURE REGARDING PROPOSED EXPERT TESTIMONY

A. Background

21. The API in Zydus's ANDA Products is canagliflozin, which has the chemical name (1S)-1,5-anhydro-1-[3-[[5-(4-fluorophenyl)-2-thienyl]methyl]-4-methylphenyl]-D-glucitol and the following chemical structure:



(ZYDUS-INVOKA00441482 at 502; *see also* ZYDUS-INVOKA00441940 at 969-970).

22. I understand that canagliflozin may exist in different solid forms, including amorphous, crystalline anhydrous, crystalline monohydrate, and crystalline hemihydrate. (Ex. 3, U.S. Patent. 7,943,582; Ex. 4, U.S. Patent No. 8,513,202; Ex. 5, U.S. Patent Application 2008/0155329; Ex. 6, WO 2016/136830.)

23. Crystalline forms are solids made up of organized molecules arranged in a regularly repeating three-dimensional array known as a crystal lattice. An amorphous solid form is a non-crystalline solid form. In an amorphous form, the molecules are arranged randomly.

24. [redacted]

25. In general, PXRD is an analytical technique that can be used to identify the structure of a solid state of a material and, more specifically, to distinguish between different solid state forms of the same compound.

26. Raman spectroscopy is yet another analytical technique that may be used to identify solid state forms of a compound. In Raman spectroscopy, a sample is exposed to a high intensity laser light source. Molecules in the sample scatter incident light from the laser. A small amount of the scattered light is scattered at different wavelengths (or colors), which depend on the chemical structure of a compound—this is called Raman Scatter. A detector measures light that is scattered at these wavelengths. Those measurements are then processed by the instrument to create a graph called a "Raman spectrum." A Raman spectrum features a number of peaks, showing the intensity and wavelength position of the Raman scattered light. Each peak corresponds to a specific molecular bond vibration. Those vibrations can vary based on the crystal structure of the compound. Therefore, Raman spectroscopy can be used to distinguish between different solid state forms of the same compound by determining the vibrational modes of the molecules to provide a structural fingerprint by which the molecules can be identified.

27. This report discusses two different types of Raman techniques. FT Raman uses an instrument that generates a Raman spectrum for an entire sample. The other type of Raman, Raman microspectroscopy, allows the user to isolate a particular component in a heterogeneous mixture and generate a Raman spectrum for that particular area of the sample. For example, Raman microspectroscopy can be used to analyze particles that are present in APIs to determine the solid state form of each particle. In this report, I will refer to Raman microspectroscopy as "Raman," to distinguish it from FT Raman.

28. Polarized light microscopy is an analytical method that utilizes a microscope equipped with crossed polarizers that can be employed to search for crystalline particles in a mixture of allegedly amorphous material. A polarized light microscope illuminates a sample with polarized light. [redacted].

B. Materials and Methods

29. All of the experiments I performed were conducted in my laboratory at Solvias AG, in Kaiseraugst, Switzerland.

a) Instrumentation

30. The Raman microscope system and the X-ray diffractometers are performance tested and calibrated on a regular basis according to written test procedures. The Raman

microscope system is tested each day before it is used and the X-ray diffractometers are tested once a month and a quick test is done each day before use. The instruments satisfied the performance test specification during that period. (Ex. 7.)

31. **Polarized light microscopy:** The optics of a polarized light microscopy consists of an eyepiece and an objective lens. The magnification is the product of the eyepiece magnification and the objective lens magnification. Light microscopy was performed with two light microscopes. [redacted] I then used the Leica DML microscope polarized light microscope incorporated into the Raman system described below. For the Leica DML microscope, I used a 10x20 magnification and a 10x50 magnification. (For both microscopes the eyepiece magnifies 10x).

32. **Raman:** Raman measurements were carried out using a dispersive Renishaw RM1000 system combined with a Leica DML microscope. The dispersive Renishaw instrument generates a Raman spectrum by exposing the sample to a stabilized diode laser at 785 nm, which is typically operated with about 50-100% laser power. The laser power used depends upon the size of the particles and the amount of material that is hit by the laser beam. If the signal is too high the detector is saturated for the most intense Raman bands and a second run with reduced laser power should be performed. The laser spot has an elliptical shape. When using the 10x20 magnification, the spot size is about 20 µm x 50 µm, at the 10x50 magnification, the spot size is about 10 µm x 30 µm. The system detects the Raman scatter from the sample with an NIR enhanced Peltier cooled CCD camera as the detector. Typically, the selected wavenumber range was from 1900 to 300 cm^{-1}. The exposure time was 10 seconds. One to five accumulations,

depending on signal intensity, were recorded for each analysis. The instrument is operated by the WiRE 2.0 software package and further data evaluation was carried out with the Bruker OPUS software version 7.0.129.

33. **PXRD**: Powder X-ray diffraction was carried out with a Stoe Stadi P diffractometer equipped with a Mythen1K detector operating with Cu-$K_{\alpha 1}$ radiation. The measurements with this instrument were performed in transmission at a tube voltage of 40 kV and 40 mA tube power. A curved Ge monochromator allows testing with Cu-$K_{\alpha 1}$ radiation. The following parameters were set: 0.02° 2θ step size, 48 s step time, 1.5-50.5° 2θ scanning range, and 1° 2θ detector step (detector mode in step scan). For a typical sample preparation about 10 mg of sample was placed between two acetate foils and mounted into a Stoe transmission sample holder. The sample was rotated during the measurement.

b) Samples

34. I was sent one batch of Zydus's API by Karen Gushurst at AMRI SSCI, LLC ("SSCI") in West Lafayette, Indiana. (Ex. 8.) The shipment was received at Solvias AG on May 2, 2019. The Sample and Order Logistic ("S&OL") Team at Solvias AG, which is responsible for processing any shipments received from customers, processed the sample upon receipt. The S&OL Team checked the packing list enclosed with the shipping papers against the contents in the shipment (i.e., the labels on the glass vials) and confirmed that we had received the materials identified by SSCI. The S&OL team then registered/logged the Zydus API sample into the Solvias Library Information Management System ("SLIMS") system. A member of that team then placed the Zydus API sample into a designated SLIMS box, which is simply a plastic box, and immediately stored the sample in our Sample Storage room at room temperature as per Zydus's specified storage conditions. (*See* ZYDUS-INVOKA00066658 at 660 ("store at

controlled room temperature i.e., between 20°C and 25°C"); ZYDUS-INVOKA 00067116 at 125; ZYDUS_INVOKA 00023333 at 341; ZYDUS_INVOKA 00000730 at 741.) I separately gave the package of Zydus's API that I received an identifying number as indicated in the table below as the "Solvias ID No."

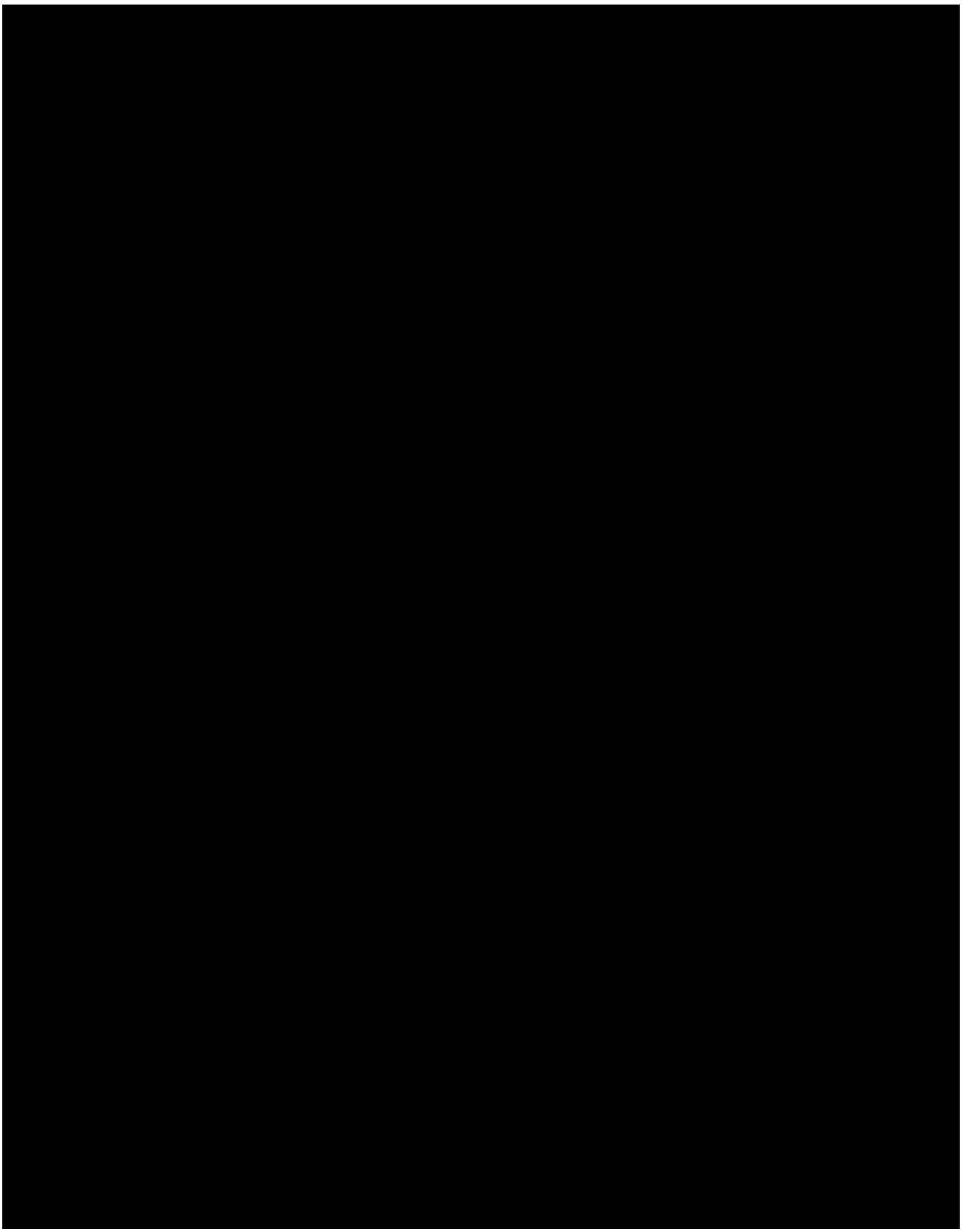
[redacted]

[redacted]

[redacted]

42. [redacted]

[redacted]



[redacted]

[redacted]

[redacted]

47. [redacted]

[redacted]

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[redacted]

50. [redacted]

51. [redacted]

52. [redacted]

[redacted]

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[redacted]

55. [redacted]

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61. [redacted]

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[redacted]

[redacted]

[redacted]

V. SUPPLEMENTATION

66. I reserve the right to supplement or amend my opinions in response to opinions expressed by Zydus's experts, or in light of additional evidence, testimony, discovery, or other information that may be provided to me after the date of this report.

67. In addition, I expect that I may be asked to consider and testify about issues that may be raised by Zydus's fact witnesses and technical experts at trial or in their reports. It may also be necessary for me to supplement my opinions as a result of ongoing discovery, Court rulings and testimony at trial.

VI. TRIAL EXHIBITS

68. I may rely on visual aids and demonstrative exhibits that demonstrate the bases for my opinions. These visual aids and demonstrative exhibits may include, for example,

interrogatory responses, deposition testimony and exhibits, as well as charts, photographs, diagrams, videos, and animated or computer-generated videos.

VII. CONCLUSION

69. As set forth above, it is my opinion that the experiments I have been asked to perform on Zydus's API and the Janssen reference samples reliably generated light microscopy images and Raman spectra for those samples provided to me, as set forth above.

Executed this 5th day of February 2020. I declare under penalty of perjury that the forgoing is true and correct.

Fritz Blatter, Ph.D.